



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	11/14	FIRST NAMED APPLICANT	N	APPLY DOCKET NO.
--------------------	-------------	-------	-----------------------	---	------------------

18M1/0924
BIRCH STEWART KOLASCH AND BIRCH
P O BOX 747
FALLS CHURCH VA 22040-0747

EXAMINER

LUCAS, J

ART UNIT

PAPER NUMBER

1806

09/24/97

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 6/13/97

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1-8 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
 Claim(s) _____ is/are allowed.
 Claim(s) 1-8 is/are rejected.
 Claim(s) _____ is/are objected to.
 Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of Reference Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1806

Part III DETAILED ACTION

1. Claims 1-8 are pending and will be examined on the merits.

Claim Rejections - 35 USC § 112

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

The specification fails to enable one of skill in the art how to search and evaluate substances effective for prevention or therapy of bone disorders. The specification does not disclose how to screen for substances that will have the desired affect in vivo of inducing IFN. The specification has not disclosed how to determine whether substances screened in vitro will have the same affect in vivo. The substances may not reach there desired target, may be toxic, may not induce IFN due to other negative factors present in vivo, may not induce IFN in the necessary location of the body, the induced IFN may not be produced in the necessary quantities (too much or too little) and no method of determining how much of the evaluated substance to administer to achieve the desired results, etc. Without a method for searching and evaluating for substances effective for the prevention or therapy of bone disorders by inducing IFN the claimed invention would not be enabled. Therefore, in view of the lack of guidance

Art Unit: 1806

in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention as it pertains to searching and evaluating for substances effective for the prevention or therapy of bone disorders by inducing IFN.

2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 provides for the use of IFN- β , but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 6 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Art Unit: 1806

3. Claim 3 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 1 is drawn to IFN- β . Claim 3 is drawn to either IFN- α , β , or γ .

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Gomi et al. (J. Pharmacobio. 1986) or Michalevicz (U.S. Patent 5,104,653). The claims are drawn to a drug for treating bone disorders comprising IFN- β and a method for treating bone disorders comprising using IFN- β .

Gomi et al. teach IFN- β and a method of using IFN- β to treat human osteosarcoma, a tumor related bone disorder (see abstract). All the limitations have been met.

Michalevicz teaches IFN- β and methods of using IFN- β to stimulate erythropoiesis which occurs in the bones and is therefore broadly defined as a bone disorder. Michalevicz teaches using IFN- β to stimulate erythropoiesis in patients suffering from anemia, myelofibrosis, CML (a tumor related bone

Art Unit: 1806

disorder) and rheumatoid arthritis (see claims 1-10 for example). All the limitations have been met.

6. Claims 1, 3, and 4 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Lyndon et al. (J. Pediatr. 1992). The claims are drawn to a drug for treating bone disorders including metabolic disorders and bone fractures wherein the drug comprises IFN- γ .

Lyndon et al. teach using IFN- γ for treating osteopetrosis (broadly defined as a metabolic disorder which leads to bone fractures) with IFN- γ (see abstract). All the limitations have been met.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John M. Lucas whose telephone number is (703) 305-6838. The examiner can normally be reached on T-F from 7:00am to 6:00pm EST.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 305-3014 or 305-7939.

Art Unit: 1806

10. Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [lila.feisee@uspto.gov].

11. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

John M. Lucas, PhD

14 September 1997

Lila Feisee
Supervisory Patent Examiner
Group 1800